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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,648	04/13/2000	Zeling Cai	ORT1224	6532

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/548,648	**Applicant(s)** CAI ET AL.	
	Examiner G. R. Ewoldt, Ph.D.	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *01 February 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3 and 5-7*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

3/2006

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

DETAILED ACTION

1. Claims 1, 3, and 5-7 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A method for the detection of antigen specific T cells, comprising:

a. providing a recombinant cell expressing an MHC class I protein-fluorescent protein fusion molecule or a radiolabeled MHC class I protein on a surface of the recombinant cell;

b. contacting the MHC class I protein-fluorescent protein fusion molecule or the radiolabeled MHC class I protein, bound to a specific antigen with a population of T cells;

c. incubating the fusion molecule or the radiolabeled MHC class I protein bound to the specific antigen together with the population of T cells for a period of time sufficient for the T cells to internalize the fusion molecule or the radiolabeled MHC class I protein from the T cell surface; and

d. identifying the T cells that have internalized the fusion molecule or the radiolabeled MHC class I protein (Claim 1).

Page 5, lines 8-10 of the specification disclose, "L^d-GFP expressing cell lines were used as antigen presenting cells (APCs) to present specific QL9 peptide (7) to $CD8^+$ T-cells from the 2C TCR transgenic-mouse line (2C T-cells), which specifically recognize the T-cell antigen QL9 (8)." It is unclear how this disclosure supports the method as now claimed.

A review of the application shows that the generic method of the original claims comprised a method for the purification of T cells comprising contacting T cells with an MHC class I protein associated with a specific antigen. The newly claimed limitation of part a) of Claim 1, providing a recombinant cell expressing an MHC class I protein-fluorescent protein fusion molecule or a radiolabeled MHC class I protein on a surface of the recombinant cell was not present in the original claims. Accordingly, support for the new limitation to the generic claim must be found in the specification.

A review of the specification reveals little generic disclosure of the invention. The specification consists generally of the same teachings as the newly submitted Huang et al. (1999) reference, i.e., specific experiments employing a specific cell type, specific recombinant MHC class I constructs, and a specific antigen. Such a disclosure is insufficient support for the generic method of the claims, i.e., a method employing any recombinant cell, any recombinant MHC class I construct, and any antigen.

Applicant's remarks, filed 5/27/05, assert that support for Claim 1 can be found at pages 1, 4, and 5 of the specification.

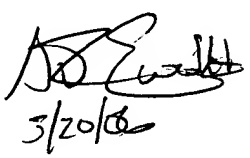
A review of the specification shows that it discloses a method of detecting antigen specific T cells (page 1), however, said method is not disclosed in a context

employing a generic "recombinant cell" expressing a generic MHC Class I-green fluorescent protein (GFP) fusion molecule or radiolabeled MHC Class I. The specification discloses only the method employing specific *Drosophila* cell lines (see Cai et al. PNAS, 1996), expressing specific MHC Class I L^d-GFP vectors, presenting specific antigens, e.g., QL9 peptide (pages 4-5).

Applicant's arguments, filed 12/05/05 have been fully considered but they are not persuasive. Applicant argues new cites in the original specification and claims support the method as now claimed.

Applicant is advised that merely finding the words comprising the instant claims at various cites throughout the specification does not support the method of the instant claims.

First note that Applicant begins by citing original Claims 1 and 2. Original Claim 1, however, recites a method for the purification of Ag-specific T cells and not the claimed method for the detection of Ag-specific T cells. Applicant then cites page 1, lines 15-22 of the specification. While this cite does disclose detection of Ag-specific T cells, it does not disclose any particular method for said detection and said detection is only disclosed only as "a means to detect the presence of, and to quantify, T cells specific for a particular antigen present in a mixed population of T cells specific for a multitude of antigens". Applicant then cites page 5, lines 1-5 in support of the detectable markers of the claims. The cite at page 5 comprises the end of a paragraph disclosing the generation of *Drosophila* cell lines prepared "to investigate the fate of MHC/peptide complexes on APCs after engagement of T-cells". This final cite in particular comprises a clear example of asserting support for the claimed method employing cites disclosing the words recited in the claims, but disclosing them completely out of the context of the method of the instant claims. Accordingly, it remains the Examiner's position that the specification and claims as filed do not support the method as now recited.



3/20/06

G.R. EWOLDT, PH.D.
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